UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

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SPRUNG HORN KRAMER & WOODS
600 THIRD AVENUE
NEW YORK, NY 10016

EXAMINER	
TOUPAL	
ART UNIT	PAPER NUMBER
1219	13

DATE MAILED: 02/02/88

This is a communication from the examiner in charge of your application.

COMMISSIONER OF PATENTS AND TRADEMARKS

☐ This application has been examined ☑ Responsive to communication filed on October 5 1987 (November 2) ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), 0 days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☑ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice re Patent Drawing, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449
4. ☐ Notice of Informal Patent Application, Form PTO-152
5. ☐ Information on How to Effect Drawing Changes, PTO-1474
6. ☐ _____

Part II SUMMARY OF ACTION

1. ☑ Claims 1-7 and 11 are pending in the application.
   Of the above, claims _____ are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☑ Claims 1-7 and 11 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings which are acceptable for examination purposes until such time as allowable subject matter is indicated.
8. ☐ Allowable subject matter having been indicated, formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. These drawings are ☐ acceptable; ☐ not acceptable (see explanation).
10. ☐ The ☐ proposed drawing correction and/or the ☐ proposed additional or substitute sheet(s) of drawings, filed on _____. has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved. ☐ disapproved (see explanation). However, the Patent and Trademark Office no longer makes drawing changes. It is now applicant's responsibility to ensure that the drawings are corrected. Corrections MUST be effected in accordance with the instructions set forth on the attached letter "INFORMATION ON HOW TO EFFECT DRAWING CHANGES", PTO-1474.
12. ☐ Acknowledgment is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claims 1-7 and 11 are in the case.

Claims 1-7 and 11 are rejected under 35 U.S.C. 112, first paragraph, as the disclosure is enabling only for claims limited in accordance with the specific examples. See MPEP 706.03(n) and 706.03(z).

The term "warm blooded animals" in claim 1 remains rejected for the reasons stated in the last Office action, see paper No. 8. The term "human cells" in claim 11 is too broad since the said term includes bone cells, brain cells, or nerve cells, etc. It should be limited to the human cells tested.

Applicant's arguments filed October 5, and November 2, 1987 have been fully considered but they are not deemed to be persuasive.

Evidence of significant human clinical studies is ordinarily required to support the claims to a method of treatment including humans where the effectiveness can not be predicted. The issue herein is not the amount of in vitro examples, but whether an in vitro utility is sufficient to establish an in vivo utility for the claimed compound. The decisions of Ex parte Chwang, Ex parte Krepelka, and In re Hirsch cited by the applicants

have been carefully considered, however, they are not controlling herein. Each case must be dealt with on its own merit. In the absence of animal tests or any data in the record which correlates tests conducted in tissue culture with the disease to be treated, there lacks an enabling disclosure for the term "warm blooded animals" and "human cells".

The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 1-7 and 11 are rejected under 35 U.S.C. 103 as being unpatentable over the Veheyden et al patent, of record or the Japanese patent '783 in combination with the Robins report.

The Veheyden et al patent generically discloses antiviral activity of 2', 3'- unsaturated nucleosides which includes 5-alkyl-2',3'-unsaturated uridines (see the sugar formula I in column 2, line 20 and the base formula in column 2, line 35, in particular). The

5-alkyl can be 3-7 carbons in length which are a homolog of the instant compound, 3'-deoxythymidin-2-ene which is 5-methyl. The Japanese patent '783 also discloses antiviral actions of 2'.3'-unsaturated nucleosides which encompass the instant 3'-deoxythmidin-2'-ene. The use of a known antiviral compound for treating applicants' particular viruses that are a retrovirus, a MuLV or HIV virus is deemed obvious to a person of ordinary skill in the art in view of the teaching of the Robins report which discloses that an antiviral nucleoside such as ribavirin which has a broad spectrum of antiviral activity for inhibiting DNA and RNA viruses is also effective in treating a retrovirus, a MuLV or HIV virus, see the last page in particular.

Applicants' arguments filed October 5 and November 2, 1987 have been fully considered, but they are not deemed to be persuasive with regard to the present rejection.

Any inquiry concerning this communication should be directed to J. Tou at telephone number 703-557-3327.

JT
J. Tou:klw
1-18-88
(703) 557-3327

Johnnie R. Brown
J. R. BROWN
SUPERVISORY PATENT EXAMINER
ART UNIT 123